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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,631	12/03/2005	Moon-Hee Sung	4240-134	5032

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,631	SUNG ET AL.	
	Examiner	Art Unit	
	Benjamin P. Blumel	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 24, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *3 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 6-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/3/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of required species in the reply filed on September 24, 2007 is acknowledged. The traversal is on the ground(s) that the claimed species share a special technical feature since the spike proteins are components of SARS viruses, pgsA-pgsC are poly gamma glutamate synthase genes and the microorganisms of claim 7 do not show toxicity upon application to a living body. This is not found persuasive because even though the claimed SARS antigens are from a SARS virus, these are different antigens and would therefore require a different search, especially since each is encoded by a different ORF. Furthermore, the election requirement of a specific microorganism is also maintained because the organisms listed, as pointed out by the applicant, are distinct merely based on gram positive/negative phenotypes and also considering that mycobacterium species, staphylococci species and *E. coli* a few of the unrelated microorganisms. With regard to applicants assertion that the claimed microganisms have low toxicity in a living body, this doesn't make sense given the virulence (toxic shock) that some Staphylococcus, Salmonella and Vibrio species have when humans are infected. However, the election requirement for the pgs complex genes is withdrawn.

The requirement is still deemed proper and is therefore made FINA L.

Claims 3 and 5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 24, 2007.

Claims 1, 2, 4 and 6-19 are examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 3, 2005 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 6-8, 14 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over Sung et al. (US 2005/0249752 A1) and Ho et al. (Biochemical and Biophysical Research Communications, 2004).

One of the applied references has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The claimed invention is drawn to a recombinant *Lactobacillus casei* that expresses the SARS SC spike protein along with the pgsA gene in the plasmid pHCE2LB resulting in the construct pHCE2LB:pgsA-SARS SC. The spike protein is expressed on the surface of the bacteria and the spike protein is produced through culturing the recombinant bacteria.

Sung et al. teach the development of recombinant *Lactobaccillus casei* bacteria that expressed Human Papillomavirus antigens inserted into a pHCE2LB vector which also expresses pgsA, pgsB and/or pgsC. Based on the teachings of Sung et al. and the specification of the instant application, the recombinant bacterial-vector systems are the same. However, Sung et al. do not teach expressing SARS antigens in place of the HPV antigens.

Ho et al. teach the expression of a SARS spike protein by *E. coli*. The S (spike) gene, including SARS SC, was ligated into a vector, and then inserted into the *E. coli* cell. The recombinant bacteria were propagated and the spike proteins were harvested, then purified.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Sung et al. in order to generating a recombinant *Lactobacillus casei* that contains the pHCE2LB:pgsA-SARS SC vector. One would have been motivated to do so, given the suggestion by Sung et al. that the bacterium be used to express antigens of interest. There would have been a reasonable expectation of success, given the knowledge that SARS spike proteins can be expressed by bacteria through an expression vector/plasmid, as taught by Ho et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-13 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing antibodies in mice against recombinant *Lactobacillus casei* expressing SARS spike SA and SC and nucleocapsid NB antigens, does not reasonably provide enablement for a vaccine for SARS or preventing SARS through a vaccine administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use or make the invention commensurate in scope with these claims.

Nature of the invention/Breadth of the claims. The claimed invention is drawn to a vaccine for preventing SARS infections.

State of the prior art/Predictability of the art. The state of the art does not recognize any vaccine for SARS virus. For example, both Wang et al. (Microbes and Infection, 2007 and Taylor (Vaccine, 2006) state that no vaccine is available for treating/preventing SARS infections. More specifically, Taylor summarizes the state of SARS vaccine research by stating that much is still unknown with regard to viral pathogenesis (page 869) and Wang et al. states that no specific treatment exists for SARS (abstract).

Working examples. One working example exists relating to *in vivo* usage of recombinant *Lactobacillus casei* expressing SARS spike SA, spike SC or nucleocapsid NB antigens for producing reactive antibodies in mice. However, these inoculated mice

were not challenged with a virulent strain of SARS virus, nor were the reactive antibodies tested for at least *in vitro* neutralization activity. Furthermore, since the SARS spike proteins are largely glycosylated, the recombinant SARS antigens produced in the instant invention do contain all of the antigenic domains because prokaryotes, such as *Lactobacillus casei*, do not glycosylate proteins. In addition, even though reactive antibodies were isolated from inoculated mice, it is unclear what portion of these antibodies were capable of neutralizing infectious SARS virus, since antibodies may be reactive, but not capable of stopping SARS virus from infecting target cells.

Amount of experimentation necessary. Therefore, additional research is required in order to determine how effective a SARS vaccine is at treating at risk hosts in order to reduce the risk of infection.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin P Blumel/
Examiner
Art Unit 1648

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